

**Simplot Responses to Agency Comments (October 20, 2015),  
Updated to Reflect Agency Communications (November 2015),  
and Agency Responses to Simplot Responses (December 1, 2015), on the  
“Revised Draft Site-Specific Ecological Risk Assessment Report,  
Smoky Canyon RI/FS” (Dated September 2015)**

**Specific Comments**

- 1) **Page 9, Last Paragraph:** Please clarify if any selenium hyperaccumulating plants were identified on Site from investigations prior to the RI data collection efforts. This information would be helpful in potential long-term remediation alternatives (hyperaccumulating plants noted on site prior to the herbicide program may indicate the need for continuation of such a program as a remediation alternative).

**Simplot Response (November 10, 2015):** The pre-RI vegetation studies will be reviewed for the presence or absence of hyperaccumulating plants and the results will be discussed in the revised text.

- 2) **Page 60, Selenium bullet:**

- a) The text states that “For selenium, the TRV used for tissue was the egg/ovary effects threshold value translated to whole body tissue concentrations (e.g., 20.5 mg/kg dw) divided by the egg to ovary translation factor (1.45).” However, in Appendix D, the text states that a range of endpoint measurements would be used including the EPA-derived 18.09 mg/kg dw. Please clarify.

**Simplot Response (November 10, 2015):** A range of endpoints was used in the SSERA. The lower of the two EC10 values (EPA’s EC10 for brown trout) was used in screening and Tier 1. This provided for a conservative screening process. The less conservative EC10 for brown trout, derived by Simplot, was used in Tier 2 and 3. To avoid confusion, both values will be carried through the SSERA for each Tier.

- b) Please clarify if the Presser and Luoma (2010) model was the translation method recommended by EPA in the Draft 2015 National Criterion, and if not, please revise to use the method recommended by EPA in the Draft Criterion.

**Simplot Response (November 10, 2015):** The Presser and Luoma Model (2010) is the basis for the USEPA method illustrated in the 2015 Draft National Criterion. To clarify the statement in the SSERA, the following text will be added: “Finally as an additional assessment, the site-specific tissue criterion value was translated to a selenium water concentration value using the Presser and Luoma (2010) model as modified by USEPA in the 2015 Draft Criterion....”

- 3) **Page 60, Iron Bullet:** Please clarify that at certain levels, iron can also become toxic.

**Simplot Response (November 10, 2015):** The text will be revised to clarify that iron can be toxic at levels exceeding nutritional requirements.

- 4) **Page 61, Zinc Bullet:** The text states “As for copper and iron, zinc is an essential micronutrient.” Please clarify that at certain levels, zinc can also become toxic.

**Simplot Response (November 10, 2015):** The text will be revised to clarify that copper, iron, and zinc can be toxic at levels exceeding nutritional requirements.

- 5) **Pages 77-78, Section 4.3.4, Copper:** Summary tables providing the HQs for the alternative TRVs and geometric mean TRVs were provided in the Section 4 tables for all terrestrial ECOCs with the exception of copper. Please add these summary tables to the SSERA.

**Simplot Response (November 10, 2015):** Calculations using the geometric mean and/or other alternative TRVs were not provided for copper due to the uncertainty in the copper data within several of the small mammal tissue samples. Several alternative TRVs were provided in Table 6-1 of the BPF and can be used for calculations in the SSERA, however, their use will not preclude the recommendation that additional small mammal samples be collected in order to attempt to reduce the uncertainty regarding copper as discussed in the SSERA.

**Agency Response (December 1, 2015) to Simplot Response:** Please clarify in the text that additional small mammal sampling will be conducted in 2016 to try to constrain the uncertainty associated with the copper data.

**Simplot Response (December 29, 2015):** The report has been revised to state that a proposed plan for additional sampling of small mammal tissues in the areas where the suspected anomalous copper results were observed will be provided to the agencies in early 2016. Collection of the samples is expected in the summer of 2016.

- 6) **Pages 81-83, Section 4.3.4, Selenium:** The Tier 3 risk characterization discussion for selenium is focused on areas that may have lower risk and largely ignores describing the risk in areas calculated to have higher risk (e.g., Pole Canyon ODA). The higher risk areas are only used to indicate that low risk areas are below those at Panel A Area 2, Pole Canyon ODA, and Panel D North and South areas. The conclusion provided is “the potential for effects within the Panel A Area 2, Pole Canyon ODA, and Panel D North and South areas may be higher than is the other areas of the Site.” The vague characterization provides little for risk managers. Considering this is the Tier 3 characterization which uses less conservative TRVs and relies on a large data set of site-specific abiotic and biotic tissue concentrations rather than less certain modeled concentrations, the risk characterization discussion should be more conclusive. Please provide a more detailed description of the risk posed by Panel A Area 2, Pole Canyon ODA, and Panel D North and South areas.

**Simplot Response (November 10, 2015):** The Tier 3 Risk Characterization was written to provide risk managers with data by which the potential for risks within each area of the Site could be compared relative to other areas of the Site. As such, the discussion is focused on discussing areas of the Site where previous efforts are shown to be successful in reducing exposure and potential risk. We believe that this is a valuable line of evidence for risk managers. The revised text will include additional discussion regarding the relative differences in exposure and potential risk

within both those areas where exposure is relatively low and in those areas of the Site where exposure is highest.

- 7) **Page 87-88, Section 4.3.4, Zinc:** Please reference Table 4-34 in this section.

**Simplot Response (November 10, 2015):** Table 4-34 is referenced in Section 4.3.4 in the fourth paragraph under the “Zinc” sub-heading.

- 8) **Page 87-88, Section 4.3.4, Zinc:** Alternative TRVs and geometric mean TRVs were provided for all terrestrial ECOCs with the exception of zinc which relies only on an alternate LOAEL. Please explain why geometric mean TRVs are not included as occurred with other ECOCs.

**Simplot Response (November 10, 2015):** Where applicable, the geometric mean NOAEL TRV was used in Tier 3. That value was only applicable in cases where the EcoSSL selected a NOAEL TRV that was lower than the geometric mean NOAEL TRV. For zinc, the EcoSSL guidance selected the geometric mean NOAEL TRV as the NOAEL TRV and it was used in the SSERA for the avian NOAEL for zinc. As a result, the LOAEL TRV (131 mg/kg BW/day) was selected as an alternative TRV based on its publication by Sample et al. (1996).

The alternate LOAEL TRV selected is from a study that used test dosages separated by an order of magnitude (NOAEL = 14.5 mg/kg-bw/d and LOAEL = 131 mg/kg-bw/d). Therefore, due to the large gap between dosages, the confidence in relying on this LOAEL TRV is low. This is supported by the more recently published and highly peer reviewed Eco-SSL document providing 18 reproductive, growth, or survival LOAELs below the 131 mg/kg-bw/d) that has been selected.

**Simplot Response (November 10, 2015):** The NOAEL TRV for zinc effects to birds (66.1 mg/kg BW/day) was used in the SSERA in all NOAEL HQ calculations. That value was equal to the geometric mean of NOAEL TRVs as presented in the EcoSSL guidance document. The geometric mean NOAEL TRV was selected by EcoSSL for use as a NOAEL because it was lower than the lowest bounded LOAEL TRV for birds presented in that document (66.5 mg/kg BW/day). The lowest bounded LOAEL TRV for birds was used in all LOAEL HQ calculations preceding Section 4.3.4. The alternative TRV selected (131 mg/kg BW/day) was selected based on its publication in several widely used TRV databases as a LOAEL value and it provides another comparison point for risk managers. HQ calculations using only the lowest available effects-based (i.e. LOAEL) TRVs can overestimate risk significantly particularly when population level Assessment Endpoints are the focus of the risk assessment, as is the case at the Smoky Canyon Mine. Alternative TRVs are, therefore, provided as an additional reference point for risk manager's use in decision making per USEPA guidance (USEPA 1997 and USEPA 1998). Additional discussion regarding the zinc TRVs selected for use in the SSERA will be provided in the text. Please see the response to Specific Comment 13 for additional discussion.

**Agency Response (December 1, 2015) to Simplot Response:** Simplot's main argument in the previous response is the following: "HQ calculations using only the lowest available effects-based (i.e. LOAEL) TRVs can overestimate risk significantly particularly when population level Assessment Endpoints are the focus of the risk assessment..." However, the Agencies believe that the lowest LOAEL should be used when it is based on an endpoint relevant to population-level effects, such as the reproduction endpoint in this case. This is also consistent with the approach the Agencies have directed throughout the SE Idaho mine sites.

Specific to zinc, a similar discussion of an appropriate avian LOAEL has occurred between the Agencies and mining company representatives at the Champ and Mountain Fuel Mine sites. The resulting LOAEL agreed upon is described below:

As with Smoky Canyon, the selected NOAEL TRV of 66.1 mg/kg bw-d is based on the geometric mean of the NOAEL values for reproduction and growth endpoints (n = 43). The lowest bounded LOAEL value is reported as 66.5 mg/kg bw-d in Table 5.1 of the EcoSSL documents (USEPA 2013) based on a study conducted by Gibson, Stevenson, and Jackson (1986). This LOAEL is based on the reduced progeny count (reproductive endpoint) in 30-week-old chickens exposed to zinc acetate for 10 weeks in their diet. However, upon additional review of the study, Arcadis determined that the LOAEL value appears to have been calculated incorrectly. In the study, the reported LOAEL was for "added" zinc. The study provides a concentration of 34 mg/kg diet of zinc that was also included in the diet. Correcting for the measured body weight and ingestion rate for the LOAEL-specific dose group reported in the study and including the concentration of zinc that was a part of the control diet, the LOAEL is 79.3 mg/kg bw-d.

Based on this correction in dietary dose, the lowest LOAEL reported in the EcoSSL document that is above the NOAEL is 76.7 mg/kg bw-d (Stevenson, Jackson and Gibson, 1986). However, like the Gibson, Stevenson and Jackson (1986) study, this study also included a concentration of zinc in the basal diet that was not accounted for in the EcoSSL dose conversion. When the zinc in the basal diet is included with the "added" zinc, the dose from this study is not the lowest value. Thus, the value of 79.3 mg/kg bw-d from the Gibson, Stevenson, and Jackson (1986) study was selected and approved as an appropriate LOAEL TRV. This LOAEL TRV is lower than the Sample, Opresko, and Suter (1996) LOAEL value of 131 mg/kg bw-d and is recommended for the Smoky Canyon ERA.

**Simplot Response (December 29, 2015):** Based on review of the Gibson et al. (1986) report, we agree that recalculation of the lowest LOAEL TRV is a reasonable step as outlined in correspondence on November 24. However, we were unable to recalculate the 79.3 mg/kg BW-day TRV provided in the comment. Our calculations are detailed in Table C-9 and resulted in a TRV equal to 79.8 mg/kg BW-day which is used as the revised lowest LOAEL TRV in the Tier 3 Risk Characterization.

- 9) **Tables 4-18, C-7 and C-8:** Table 4-18 provides the database for TRVs for both birds and mammals that are used in the SSERA. However, there are inconsistencies between these TRVs and those used in Tables C-7 and C-8. For example, Table 4-18 provides 2 selenium LOAEL-based TRVs (0.368 and 1.0 mg/kg- bw/d) for birds and 1 NOAEL-based TRV (0.61 mg/kg-bw/d). Tables C-7 and C-8 provide 4 selenium LOAEL-based TRVs (0.368, 0.93, 1.0 and 1.5 mg/kg-bw/d) for birds and 2 NOAEL-based TRVs (0.61 and 0.85 mg/kg-bw/d). The source of these additional TRVs has not been provided and their use is not supported within the SSERA. Please remove the additional TRVs from all tables as these do not appear to provide any additional value.

**Simplot Response (November 10, 2015):** The TRVs shown in the Appendix C tables include several TRVs that were provided in the BPF but not carried into the SSERA for various reasons. Only those TRVs provided in Table 4-18 were discussed or used in the SSERA for risk characterization purposes and those shown in Appendix C that do not appear in Table 4-18 will be removed.

- 10) **Section 6:** Please include a concise tabular summary of the conclusions of the SSERA. The summary should list which ECOCs and areas have been identified as posing unacceptable risk. These ECOCs would be the contaminants either requiring additional evaluation or for which risk managers will make recommendations on whether remedial alternatives will be evaluated in the feasibility study (FS) to address the risks. Selenium contamination has been identified as being the most widespread in the RI and to pose the greatest risk in the SSERA, so it is expected to be the focus of remedial action decisions. However, remedial decisions at the Site will need to be protective of exposure to all ECOCs identified. For example, preliminary cleanup levels will need to be provided in the FS (and later cleanup levels in the ROD) for each ECOCs identified in the SSERA as posing a potential unacceptable risk.

**Simplot Response (November 10, 2015):** The SSERA does not identify acceptable or unacceptable risk. The SSERA provides only a discussion of potential risk and provides data and risk-based conclusions to the risk managers for determination of what constitutes an unacceptable level of risk. As discussed in Section 6, selenium is identified as the ECOC which is driving risk estimates and the potential need for risk management decisions at the Site. All other ECOCs potentially requiring further consideration as part of the risk management process are also discussed in this section. Tables will be added to summarize the conclusions for each ECOC (refer to Tables 6-2 and 6-3). Development of preliminary or other cleanup levels is outside of the scope of the SSERA part of the FS process.

- 11) **Page 106, 1<sup>st</sup> paragraph after the bullets, 4<sup>th</sup> sentence:** The text states “The primary sources of selenium in surface waters downstream from the Site (e.g., Hoopes Spring and South Fork Sage Creek springs) are currently being treated under a treatability pilot study designed to reduced selenium concentrations in the groundwater where it discharges to surface water.” Please delete this sentence and the subsequent sentence. As noted, the current water treatment is a pilot study which is yet to be proven to be either operational or effective for the long term.

**Simplot Response (November 10, 2015):** The sentences identified in this comment will be deleted.

- 12) **Page 105, Section 6.1, sediment, last bullet:** Please add a footnote to indicate that only a subset of the metals/metalloids was included in the metals mixture evaluation and that selenium was not included in the PEC-Q.

**Simplot Response (November 10, 2015):** A footnote will be added to the text that the PEC-Q approach is a valid approach for metals that have a consensus- based guideline. No consensus-based guideline has been developed for selenium in sediments.

- 13) **Page 108, Section 6.2, 2nd bullet:** Simplot indicates that “in order to provide more useful information on the potential range of risks” that geometric means of NOAELs should be used for comparison. This is described as being important since the NOAEL and LOAEL taken from the EcoSSL for selenium were similar. The tight NOAEL and LOAEL may also be due to a robust toxicological data set because selenium is known to have a relatively steep dose-response curve. Therefore, it would be expected that the difference between a safe dose and a toxic dose may not be large. This reviewer does not disagree that this comparison provides useful information; however, it is important for risk managers to understand why there is not a large difference between the NOAELs and LOAELs. Please clarify.

**Simplot Response (November 10, 2015):** Selection of the lowest LOAEL TRV as the sole effects-based TRV provides risk managers with a potentially overly-conservative estimate of risk. This is particularly true where population-level endpoints are evaluated as is the case at the Smoky Canyon Mine. Using the most sensitive effects-based TRV may be indicative of effects to a small segment of the population of receptors at the Site and may not indicate effects that could be measured at the population level. We agree with the reviewer that a tight gap between the NOAEL and the LOAEL is likely due to a reasonably robust toxicological dataset and that selenium has a relatively steep dose-response curve. Additional information will be provided in the revised text for all ECOCs that utilize alternative TRVs to provide better context for the rationale for use of the TRVs.

- 14) **Page 109, Section 6.2, copper:** This section describes the elevated small mammal tissue results previously measured and the resulting high HQs for carnivores/raptors. This had been identified in the previous draft SSERA and additional sampling was recommended to confirm if the tissue results are valid or possibly anomalous. It does not appear that any additional sampling was conducted in 2015. Please identify when this sampling will occur and at what point will any new data be incorporated into the RI/FS process at Smoky Canyon Mine.

**Simplot Response (November 10, 2015):** A proposed plan for additional sampling of small mammal tissues in the areas where the suspected anomalous copper results were observed will be provided to the agencies in early 2016. Collection of the samples is expected in the summer of 2016.

**Agency Response (December 1, 2015) to Simplot Response:** Please clarify in the text that additional small mammal sampling will be conducted in 2016 to try to constrain the uncertainty associated with the copper data.

**Simplot Response (December 29, 2015):** A proposed plan for additional sampling of small mammal tissues in the areas where the suspected anomalous copper results were observed will be provided to the agencies in early 2016. Collection of the samples is expected in the summer of 2016. These statements have been added to the discussion of copper in small mammals in Section 6.2 of the Final SSERA Report.

- 15) **Page 110, Section 6.2, other ECOCs:** The logic in selecting the TRV for the Tier 3 risk characterization is not well understood. Previously (on Page 108 for selenium), Simplot states that “the geometric mean NOAEL TRV should be considered as a LOAEL TRV” yet for other ECOCs, the LOAEL TRV is based on the lowest LOAEL reported in the EcoSSL reports above the geometric mean or an alternative LOAEL from another source. Additional descriptions are necessary to fully understand the selection process as it changes for different ECOCs which can be portrayed as “risk shopping.” Each of the possible LOAEL TRVs holds merit; however, the selection needs to be clearly described. The latter of the three potential LOAELs (from other sources; as for zinc) likely has more uncertainty. Please clarify.

**Simplot Response (November 10, 2015):** In cases where the geometric mean NOAEL TRV was lower than the lowest bounded LOAEL TRV, EcoSSL selected the geometric mean NOAEL as a NOAEL TRV. This is because no effects have been observed at doses lower than that dose level. In other cases where the geometric mean NOAEL TRV is higher than the lowest observed LOAEL TRV, EcoSSL selected the highest NOAEL TRV that is lower than the lowest LOAEL TRV as the NOAEL TRV. In those cases, the geometric mean NOAEL TRV serves as an effects-based (i.e. LOAEL) TRV. As discussed in the response to Specific Comment 13, in all cases where alternative TRVs are used additional discussion of the rationale for selection of the alternative TRVs will be provided.

**Agency Response (December 1, 2015) to Simplot Response:** There is concern over the use of the geometric mean of NOAELs to represent a LOAEL and the Agencies are unaware of a precedence or guidance for using this approach. It is understood that the use of the use of the lowest LOAEL above a NOAEL likely overestimates the population level effects for many species; however the use of the geometric mean of all NOAELs to represent a population level effect could understate the risk to some species. For example, a geometric mean based on multiple species or life stages has the potential to be skewed upward by less sensitive species or less sensitive life stages. Considering this, the use of the lowest LOAEL (for reproductive and survival effects) above the selected NOAEL provides greater assurance of protectiveness and is the preferred TRV. The inclusion of the geometric mean of the NOAELs as alternative LOAELs in the Smoky Canyon ERA is acceptable as part of the risk characterization/uncertainty discussion, however the potential for its underprotectiveness for some species needs to be acknowledged. In addition, Simplot should recognize that risk management decisions using the lowest LOAEL may be determined to be more appropriate.

**Simplot Response (December 29, 2015):** Additional detail has been provided in the report to provide additional context to the alternative TRVs used in the assessment. Simplot recognizes that risk management decisions will be made by taking all of the available information regarding ECOC toxicity and many other factors into account as appropriate.

#### **Editorial Comments**

- 16) **Page 109, Section 6.2, 5th bullet:** Editorial – change “copper in several of small mammal samples” to read “copper detected in several small mammal samples”.

**Simplot Response (November 10, 2015):** The requested revision will be made.

- 17) **Page 109, Section 6.2, last bullet:** Editorial – change “highest in on the Pole Canyon ODA” to read “highest at the Pole Canyon ODA”.

**Simplot Response (November 10, 2015):** The requested revision will be made.

#### **Appendix D**

##### **General Comment**

- 18) In Appendix D, Simplot is making a case for a Site-Specific Selenium Criterion for surface water based on selenium concentrations in aquatic biota collected from the Site and downstream waters. Simplot is proposing slightly different values, inputs and endpoints than were used by EPA in the 2015 Draft National Criterion. EPA relied heavily on the Smoky Canyon site-specific data, primarily the brown trout data, in deriving the draft National Criterion. In essence, EPA has already evaluated the site-specific data and determined that a selenium concentration of 18.09 mg/kg dry weight in brown trout egg/ovary or less is protective of aquatic life. As noted in the RI/FS Report and elsewhere in the draft ERA, brown trout are assumed to be the most sensitive aquatic species at Smoky Canyon Mine. In Appendix D, Simplot proposes to use a range of endpoint measurements (18.09 mg/kg dw and 20.5 mg/kg dw) to evaluate risk to aquatic receptors at Smoky Canyon Mine.

**Simplot Response (November 10, 2015):** There have been multiple attempts by USEPA and others to derive a scientifically defensible EC10 from the brown trout studies. As illustrated by the text in Appendix D, even USEPA has arrived at numerous values including a range that extends up to 21.16 mg/kg dw. The 2015 Draft National Criterion cites this range, but then settles on using the value 18.09 mg/kg dw. Simplot has utilized the data it generated and derived what it believes to be a scientifically defensible value as well. In the revised SSERA, both the USEPA derived value and the Simplot derived value will be used to estimate risks.

##### **Specific Comments**

- 19) **Page 7, last paragraph, last sentence:** The text states “To account for seasonal differences, the fall data were used to focus on periods when brown trout are forming eggs and being exposed to selenium concentrations that may ultimately affect maternal transfer of selenium



to developing embryos.” This appears to state that only the fall data were used, which would not “account for seasonal differences” in selenium concentrations in the aquatic environment, since the highest selenium concentrations occur in the spring. Please provide an evaluation of risk using both spring and fall data.

**Simplot Response (November 10, 2015):** The sentence will be revised to state, “To eliminate the seasonal differences, the fall data.....” The highest selenium concentrations occur in the late summer and fall periods when flows are low. Spring high flows dilute concentrations of selenium.

**Agency Response (December 1, 2015) to Simplot Response:** Simplot will either delete the Appendix or resolve comment #19 by adding the effect of duration of spring runoff selenium concentrations to the seasonal risk as supportive information for using fall data.

**Simplot Response (December 29, 2015):** Simplot has revised the referenced text to resolve comment 19, as requested in the Agency response.

- 20) **Page 8, 1<sup>st</sup> incomplete paragraph, last sentence:** The text states that “...the data integration process focused on areas downstream of source inputs for deriving aqueous concentrations downstream of source inputs.” This is confusing and seems to imply that only some undisclosed locations downstream of source inputs were evaluated for risk to aquatic receptors. It would seem reasonable that the closest downstream locations from the source inputs that support aquatic life would be included in the integration process. Please explain or provide a reference to where this information can be found elsewhere in this document.

**Simplot Response (November 10, 2015):** Locations downstream of source inputs that were included in the derivation of the aqueous concentrations included: HS-3 (Hoopes Spring), LSV-2C and LSV-3 (Sage Creek), LSS (Lower South Sage), CC-1A and CC-3A (Crow Creek downstream of Sage Creek). These locations will be mentioned in the revised text.

- 21) **Page 9, last paragraph:** Please delete. Revise to simply state that the effect of increasing concentrations of selenium in the aquatic environment at Smoky Canyon Mine is addressed in the Uncertainty Section of the Revised Draft ERA. Justification for deletion is provided below:
- a) The text states that “The existing discharge from the spring has been increasing in recent years.” Selenium concentrations at Hoopes Spring have been steadily increasing for 16 years and at South Fork Sage Creek Springs for almost 10 years, which is quite different than “in recent years” and has direct relevance to EPA’s concern regarding use of a fish tissue-based criterion in environments where concentrations of the contaminant of concern continue to increase in the aquatic environment.
  - b) The text also states “Simplot has installed a state of the art treatment system to reduce the selenium concentrations discharged from Hoopes Spring and South Fork Sage Creek springs.” Please delete. The “state of the art treatment system” is currently an untested treatability study. It is unknown at this time whether or not this system will perform as needed as a remedy at the Site.
  - c) The text states “How this caveat to the 2015 Draft National Criterion affects the application of a site-specific criterion to Hoopes Spring and downstream receiving

waters is an issue that will need to be evaluated as part of the FS, as it is a Clean Water Act ARAR issue and not a risk assessment issue.” The Agencies disagree that continued increases in concentrations of contaminants of concern to the aquatic environment is not a risk assessment issue. Derivation of a National Criterion by EPA is, in essence, a risk assessment.

**Simplot Response (November 10, 2015):** Simplot proposes to address this comment by clarifying the intent of the discussion. Comments 21a and 21b will be resolved by revising the description of the timing of selenium increases and the terminology associated with the water treatment pilot study at Hoopes Spring and South Fork Sage Creek springs.

For comment 21c, we agree that increasing concentrations of COCs to the aquatic environment is a risk issue. We also agree that the national water quality criterion process for selenium is a form of risk assessment. However, USEPA guidance for conducting ERAs emphasizes multiple lines of evidence and site-specific data. Using a national criterion as a benchmark in a risk assessment is a screening-level approach. When available, USEPA guidance also prioritizes use of site-specific data instead of screening-level values. Our analysis uses a significant amount of site-specific data to identify which species are present, the most sensitive species, and the best measure of toxicity – which turns out to be selenium concentrations in tissues. This is consistent with similar findings for other chemicals that exert effects through bioaccumulative processes, especially in conditions of fluctuating ambient concentrations. USEPA’s 2015 Draft National Criterion is consistent with this finding, including a conclusion that tissue concentrations of selenium are superior to a water concentration-based criterion.

In Appendix D, Simplot’s statements are consistent with the findings of the USEPA process. It may turn out that discharge limits based on water selenium concentration can be identified for the Site. But USEPA has shown, along with numerous investigators including Simplot, that tissue selenium concentrations are the most reliable measure of selenium toxicity to aquatic organisms. Simplot has participated with the Agencies to derive a threshold for a sensitive species for this Site. Simplot also has the data to develop site-specific criteria and a reliable process for implementation. Therefore a national aqueous screening-level criterion<sup>1</sup> is not necessary nor is it practical.

The issue at hand is how or if the 2015 Draft National Criterion will be implemented at a site such as this or will a site-specific criterion value take precedence for remedial actions. Implementation and enforcement of a national criterion aqueous value following the assessment of risks is a policy issue, not a risk assessment issue. That is an issue to be resolved as part of the CERCLA FS, not the CERCLA risk assessment.

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<sup>1</sup> USEPA derived the lotic aqueous value based on the 20th percentile of a range of EC10 values ranging from 1.2 to 40 ug/L. Each one of those EC<sub>10</sub> is in fact a protective value for the fish species under the given conditions for the site where the data were derived.

Simplot proposes to replace the final paragraph of Appendix D with the following text:

This change added to the 2015 Draft National Criterion may have impacts on a site-specific criterion applied to Hoopes Spring and South Fork Sage Creek springs. The discharges from the springs have been steadily increasing since around 2000. Simplot is implementing a pilot study to evaluate a new treatment system technology to reduce selenium concentrations discharging from Hoopes Spring and South Fork Sage Creek springs. The pilot treatment system is currently being tested and will provide data for evaluation as part of the FS.

The manner by which the “increasing discharge” caveat to the 2015 Draft National Criterion affects application of a Site-Specific criterion to Hoopes Spring and downstream receiving waters is an issue that will need to be evaluated as part of the FS. The SSERA uses current scientific knowledge and site-specific information to estimate risks based on fish tissues and a highly relevant effect threshold measurement endpoint. This site already has a site-specific threshold developed for a sensitive species, and abundant fish tissue data are available for a site-specific bioaccumulation factor (BAF). Application of a generic numeric aqueous value derived from many locations across the nation is not appropriate when site-specific data are available. Potential risks to aquatic receptors will be present or increase as long as the concentrations in fish tissues remain above this threshold.

USEPA’s 2015 Draft National Criterion invokes a policy-based approach instead of a science-based approach to deal with uncertainty of what may occur during situations of an increasing discharge. The issue at hand is whether it is appropriate to implement the Draft National Criterion guidance at a site such as this or to use the site-specific criterion value for planning and evaluating the effectiveness of potential remedial actions. Implementation and enforcement of a national criterion aqueous value versus a site-specific criterion following the assessment of risks is a policy issue, not a risk assessment issue. That is an issue to be resolved under CERCLA as part of the FS and not in the risk assessment.

**Agency Response (December 1, 2015) to Simplot Response:** Comment #21 c) will be resolved by deleting the section commented upon if Appendix D is retained.

**Simplot Response (December 29, 2015):** Simplot agrees to address the Agency comment by deleting the section entitled “Implications of the 2015 Draft National Criterion on the Smoky Canyon SSERA” (from the middle of page 8 through the end of page 9). By deleting this section, Simplot’s November 10 response to Agency comment 21 (above) has not been implemented.